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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/718,404

11/20/2003

Mareke Hartig

01-1425

9739

28501

7590

04/23/2009

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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

04/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/718,404

Applicant(s)

HARTIG ET AL.

Examiner

Carlos A. Azpuru

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2009.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4 and 12 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,2,4 and 12 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of the response and amendment filed 02/04/2009.

The following rejection is maintained in this action:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/36163 (Boehringer Ingelheim Pharma, Inc). in view of US Patent No. 6,623,760 (Yang et al).

Boehringer Ingelheim Pharma, Inc disclose The use of Tiotropium salts in an inhalant composition (see Abstract; page 1, lines 32-35). The patent also teaches the presence of particles less than 10 μm , for example 0.1 to 5 μm at page 10, lines 2-3. Lactose is disclosed as a carrier material for these particles in the Examples. Bohringer Ingelheim Pharma, Inc differs only in the lack of discussion concerning the particle distribution, and in particular the fine particle (respirable fraction) content.

In a related patent. Yang discloses a particle which may contain Tiotropium as well as other anticholinergics (col. 9, line 2).. Carrier include materials at col. 8, lines 36-

46, with Lactose as the preferred carrier material. Yang et al further disclose a particle distribution which may contain particles as desired by well known methods of manufacture (see col. 7, lines 56-67 to col 8, line 36). As such those of ordinary skill would have found it well within their skill to manufacture particulate composition as claimed bearing the claimed particle distribution. Further, surface area is determined by the size of the particles selected and would therefore also be obvious once a particular particle distribution is selected. Therefore, the instantly claimed particle composition would have been obvious to one of ordinary skill in the art given the teachings of Boehringer Ingelheim Pharma, Inc which teaches the chemical composition, while Yang et al teaches that particle distribution can be selected according to the desired result and is accomplished by known manufacturing techniques. The instant composition would have therefore been obvious to one of ordinary skill in the art at the time of invention given the teachings of Boehringer Ingelheim Pharma, Inc in view of Yang et al.

Response to Arguments

Applicant's arguments filed 02/04/2009 have been fully considered but they are not persuasive.

Applicant argues that because the newly amended claims read on an inhalable powder which is delivered from a synthetic polymer, the references are no longer appropriate. However, applicant is claiming a composition, not a device. The storage/delivery of the claimed powder in a polymeric material does not materially

change that composition. Indeed, this is considered an intended use of the powder since it can just as easily be administered from a metallic device with equal amounts of efficacy.

The WO' 163 reference reads on the claimed particle using lactose (a dissacharide) as a carrier (see examples). US Patent No. 6,623,760 was used for the teaching of varying particle size according to the results desired, regardless of their composition (ie. "particles as desired by well known methods of manufacture (see col. 7, lines 56-67 to col. 8, line 36). As such, the secondary reference does not require the particulate characteristics of the instant invention, which are taught by the primary reference. As such, the rejection is maintained.

The following is a new rejection of the claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,2, 4 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly amended claims refer to delivery from a material made from a synthetic polymer, however the specification clearly states that the reservoir is made from this material. Clarification is required in the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615

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